TABLE No 2: THE COMPARISON OF STENTS

	Percentage of healed struts	p-value (Chi-square test)
GENOUS vs SOLARFLEX	69.75% vs 55.21%	<.0001
GENOUS vs BLAZER	69.75% vs 56.68%	<.0001
GENOUS vs NOBORI	69.75% vs 33.96%	<.0001

TABEL No 3: THE NEOINTIMA THICKNESS

	Total struts	Ø of neointima thickness (um)
GENOUS	919	49,47 ± 16,2
BLAZER	524	31,38 ± 4,88
NOBORI	1063	13,61 ± 9,64
SOLARFLEX	1536	35,05 ± 11,7

TA-AVI Using An Investigational Self—Expandable Bioprosthesis: 30 Day Outcomes

Joerg Kempfert, Markus Schönburg, Helge Möllmann, Ardwan Rastan, David Holzhey, Hendrik Treede, Stephan Baldus, Matthias Thielmann, Daniel Wendt, Holger Schröfel, Martin Heimeshoff, Friedrich Mohr, Thomas Walther

Background: Transapical aortic valve implantation (TA-AVI) is a standard approach for high-risk elderly patients using the balloon expandable Edwards SAPIEN™. As an alternative we are evaluating the Symetis ACURATE TA™, a new self-expanding transapical bioprosthesis, in a pilot study.

Methods: This novel device, composed of a porcine biologic valve attached to a self-expandable nitinol stent, is unsheathed proximally towards the apex and is designed for anatomical orientation of the commissures and subcoronary implantation using a simple intuitive two-step deployment. The device accommodates native annular sizes of 21mm to 27mm. An Ethics Committee approved the study and all patients provided informed consent.

Results: Fifty (50) patients have been treated. Mean patient age is 83.7 ± 4.3 years, 76% are female and all presented with NYHA Class III/IV with a mean logistic EuroSCORE of 19.6 ± 6.6% and STS Score of 8.4 ± 8.1%. Forty-seven (47) implants were delivered successfully in the intra-annular and subcoronary position for a procedural success rate of 94%. There were 2 conversions to conventional surgery and 1 valve-in-valve implantation. All implants were performed off-pump. To date, at 30 days post-implant, ECHO control reveals 1 patient with paravalvular leak of +2 and the remainder with ≤ +1 and no incidence of relevant (≥ 1+) central leak. The mean aortic gradient is 12.5 ± 5.0 mmHg with a mean EOA of 1.3 ± 0.4 cm2. Two patients expired by 30 days (4% mortality rate): 1 from a nonvalve- related cause (respiratory complication) and 1 following annular dissection and subsequent conversion to surgery. There was 1 reported stroke and 7 new pacemaker implants by 30 days.

Conclusion: This preliminary 30 day data indicates good function and outcomes after TA-AVI using the device in high- risk patients with aortic stenosis. Complete primary endpoint (30 day) results from the completed study will be presented for the first time at TCT 2011.

1 Year Outcomes of Trans-catheter Aortic Valve Implantation in the UK: Comparison of Valve Type and Access Route

Daniel Blackman, Philip MacCarthy

Background: Registry data and recent randomized controlled trials have established the safety and efficacy of TAVI in certain patients. An effective multidisciplinary "Heart Team" selects patients who may benefit and tailors therapy accordingly. However, little is yet known about differences in outcomes after this selection process – according to valve type and access route. The UK TAVI Registry captures all procedures performed in the UK and tracks mortality in 100% of patients, making it one of the most comprehensive TAVI registry datasets available. We present the UK survival of patients undergoing TAVI at 1 year according to the valve type and the access route.

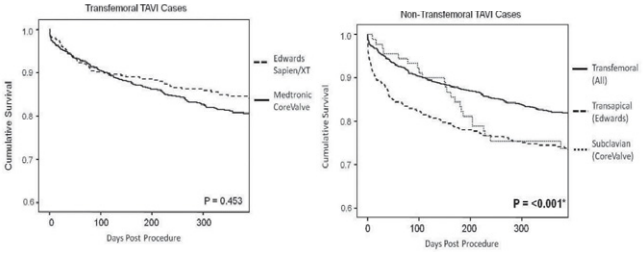
Methods: 1620 consecutive patients undergoing TAVI from 1st Jan 2007-31st Dec 2010 were analysed. Procedures were performed in 32 centres (experience range n=1-178). A comprehensive dataset was input via local databases to a central database (UK-CCAD). Mortality tracking was performed via the NHS Central Register.

Results: Patients formed 4 groups: Trans-femoral (TF) Sapien n=389 (Edwards Lifesciences, Irvine, US); TF CoreValve n=706 (Medtronic Inc, US); Trans-apical (TA) Sapien n=410; and Subclavian (SC) CoreValve n=92. Patient characteristics are shown in Table 1. Outcomes according to group are shown in Table 2. Statistical comparison is made between the Sapien TF and CoreValve TF groups and the Sapien TA and CoreValve SC groups because of their broad clinical similarity. Kaplan-Meier curves are shown comparing Sapien TF vs CoreValve TF (Figure 1) and comparing access route (Figure 2).

Conclusion: These outcomes compare favourably with published series. No difference is observed between Sapien TF and CoreValve TF at 1yr. Patient risk profile is higher with Sapien TA/CoreValve SC and mortality is higher in these groups. 30 day mortality is higher in the Sapien TA group than the CoreValve SC group but there is no difference at 1 year. The reason for this observation is not clear and requires further study. The incidence of AR>2+ and need for permanent pacing is greater with CoreValve.

	Edwards Trans-femoral	CoreValve Trans-femoral	p	Edwards Trans-apical	CoreValve Subclavian	p
n	389	706	-	410	92	-
Male, %	51.2	53.0	0.564	**52.9**	**69.6**	**0.004**
Age, mean (SD)	**82.4 (7.2)**	**81.3 (7.6)**	**0.016**	82.0 (6.8)	82.2 (6.3)	0.981
Logistic Euroscore,%	16 [11-24]	17 [12-26]	0.086	21 [14-31]	22 [13-39]	0.424
Creatinine (umol/L)	114 (58)	115 (60)	0.245	122 (69)	128 (83)	0.672
Prior cardiac surgery,%	**25.2**	**31.9**	**0.020**	39.8	30.8	0.114
PVD,%	**14.1**	**19.0**	**0.042**	**43.7**	**56.5**	**0.025**
Peak Gradient,mmHg	80 (26)	81 (28)	0.186	**77 (25)**	**83 (28)**	**0.032**
LVEF <50%,%	37.0	37.4	0.896	36.6%	43.5%	0.222

	Edwards Transfemoral	CoreValve Transfemoral	p	Edwards Transapical	CoreValve Subclavian	p
Procedural success	96.3	96.0	0.46	**97.6**	**93.5**	**0.04**
30-day mortality	4.3	5.2	0.50	**11.2**	**4.4**	**0.05**
12-month mortality	18.9	22.8	0.60	29.7	34.3	0.45
Stroke	3.0	2.8	0.64	3.7	4.3	0.76
MI	0.9	0.9	0.77	1.5	2.2	0.63
Major access site complication	8.5	6.4	0.20	2.2	5.4	0.09
New Permanent Pacemaker	**6.2**	**21.6**	**<0.001**	**5.6**	**22.1**	**<0.001**
AR ≥2+	**8.4**	**13.4**	**0.015**	6.4	9.5	0.34



Correlation between Platelet Reactivity and Type of Post-discharge Bleeding Events in PCI-treated Patients: Results of the ACCEL-BLEED study

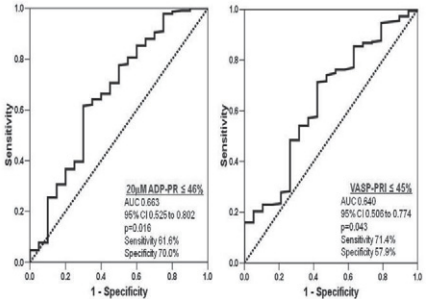
Young-Hoon Jeong, Tae Jung Kwon, Udaya S. Tantry, Yongwhi Park, Seok-Jae Hwang, Kevin P. Bliden, Choong Hwan Kwak, Jin-Yong Hwang, Paul A. Gurbel

Background: The relation of platelet reactivity (PR) to bleeding events in PCI-treated patients is unclear. Because bleeding events immediately after PCI are influenced by multiple therapies and risk factors, we evaluated whether PR correlates with post-discharge bleeding complications.

Methods: PCI-treated patients (n=252) without in-hospital complication were prospectively enrolled. Platelet measures were assessed in-hospital and at 30-day follow-up by light transmittance aggregometry (LTA) and VASP-P assay. The primary end point was the correlation of PR and 30-day incidence of bleeding events assessed by TIMI bleeding score or detailed BleedScore™.

Results: No patients suffered from TIMI major or minor bleeding. A total of 93 patients experienced BleedScore™ bleeding events (29.8%), of which 21.9% were superficial, and 7.9% were internal. Baseline demographics did not significantly differ across the bleeding type. There were no differences in in-hospital PR depending on the bleeding type. Compared to other patients, those with an episode of internal bleeding had significantly lower values of 30-day PR (VASP index, 54.8±17.3% vs. 45.2±18.7%, p=0.021; 20μM ADP-PR, 50.0±18.9% vs. 37.5±22.8%, p=0.006. By ROC curve analysis, the optimal cutoffs for predicting internal bleeding were 20μM ADP-PR at 30-day ≤46% (AUC 0.663, 95% CI 0.525 to 0.802, p=0.016) and VASP index at 30-day ≤45% (AUC 0.640, 95% CI 0.506 to 0.774, p=0.043). In multivariate analysis, 20μM ADP-PR at 30-day ≤46% was associated with a 4.5-fold increased risk for internal bleeding. VASP index at 30-day ≤45% was moderately associated with internal bleeding (OR 2.8, 95% CI 1.0 to 8.0, p=0.051).

Conclusion: Among patients undergoing PCI, ADP-induced platelet reactivity at 30-day is associated with risk for post- discharge internal bleeding. BleedScore™ bleeding scale can be utilized to assess detailed safety profile in clinical trials using potent P2Y12 inhibitors.



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